(6)

No. 89-243

In The Supreme Court of the United States October Term, 1989

ELI LILLY AND COMPANY

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

MOTION AND BRIEF FOR AMICI CURIAE SENATOR ORRIN G. HATCH AND REPRESENTATIVE CARLOS J. MOORHEAD IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETER BARTON HUTT
Counsel of Record
ELLEN J. FLANNERY
COVINGTON & BURLING
1201 Pennsylvania Avenue NW
P.O. Box 7566
Washington, D.C. 20044
202/662-5522

Counsel for Amici Curiae

10 pp

No. 89-243

In The
Supreme Court of the United States
October Term, 1989

ELI LILLY AND COMPANY

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

MOTION OF AMICI CURIAE SENATOR ORRIN G. HATCH AND REPRESENTATIVE CARLOS J. MOORHEAD FOR LEAVE TO FILE THE ACCOMPANYING BRIEF AMICI CURIAE IN SUPPORT OF THE PETITION FOR CERTIORARI

Pursuant to Rule 36.1 of this Court, *amici curiae,* the Honorable Senator Orrin G. Hatch and the Honorable Representative Carlos J. Moorhead, respectfully move this Court for leave to file the attached brief of *amici curiae* in support of the petition for certiorari. Movants have been unable to secure the

consent of the respondent.[1]

This case involves the statutory construction of 35 U.S.C. § 271(e)(1). Senator Orrin G. Hatch was the principal, if not sole, author of the legislation that was enacted into law as Section 271(e)(1). Representative Carlos J. Moorhead was the primary manager of the same legislation on the floor of the House of Representatives. The *amici curiae* have a heightened interest in having the courts properly construe Section 271(e)(1) in accordance with the Congressional intent set forth in the plain language and legislative history of the statute.

Amici curiae believe that their views will be helpful to the Court in understanding the legislative history of Section 271(e)(1) and emphasizing the importance of this case to U.S. industries involving medical devices, food additives, color additives, and other nondrug, FDA-regulated products. *Amici curiae* also believe that their views will aid the Court by addressing the legislative history of Section 271(e)(1) in detail greater than that discussed by the petitioner.

Respectfully submitted,

Dated: September 11, 1989

PETER BARTON HUTT
Counsel of Record
ELLEN J. FLANNERY
COVINGTON & BURLING
1201 Pennsylvania Avenue NW
Washington, D.C. 20044
202/662-5522
Counsel for Amici Curiae

[1] *Amici curiae* obtained the consent of the petitioner to file their brief. On Friday, September 8, 1989, *amici curiae* attempted to obtain the consent of the respondent Medtronic, Inc. pursuant to Rule 36.1 of this Court. However, respondent through its counsel declined to give its consent, and stated that respondent wanted to review the brief before it considered giving its consent.

Amici curiae informed respondent's counsel that they could not comply with respondent's request due to the time constraints and approaching deadline for the filing of briefs of *amicus curiae* in this action. Respondent's counsel then stated that its client was unavailable to authorize consent. Therefore, this motion became necessary.

QUESTION PRESENTED

Amici curiae, Senator Orrin G. Hatch and Representative Carlos J Moorhead, adopt the following question presented by petitioner Eli Lilly and Company.

35 U.S.C. § 271(e)(1) provides that "it shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products"* (emphasis added).

The question presented is:

Whether the Court of Appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. § 271(e)(1) beyond "drugs" and "veterinary biological products" to encompass, and thereby to erode patent protection for, medical devices, food additives, color additives, and all other FDA-regulated, nondrug products?

TABLE OF CONTENTS

TABLE OF AUTHORITIES

No. 89-243

In The Supreme Court of the United States October Term, 1989

ELI LILLY AND COMPANY

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

BRIEF FOR AMICI CURIAE SENATOR ORRIN G. HATCH AND REPRESENTATIVE CARLOS J. MOORHEAD IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

The Honorable Senator Orrin G. Hatch and Honorable Representative Carlos J. Moorhead submit this brief of *amici curiae* in support of the petition for certiorari in the above-identified case.

INTEREST OF THE AMICI CURIAE

Senator Orrin G. Hatch was the principal, if not sole, author of the Senate Bill which ultimately was enacted into law as 35 U.S.C. § 271(e)(1) as part of the Drug Price Competition and Patent Term Restoration Act of 1984. At that time, Senator Hatch was Chairman of the Senate Committee on Labor and Human Resources and a member of the Senate Judiciary Committee. Representative Carlos J. Moorhead was the primary manager of the legislation enacting Section 271(e)(1) on the floor of the House of Representatives. At that time in 1984, Representative Moorhead was the Ranking Republican of the Subcommittee on Courts, Intellectual Property and the Administration of Justice that processed the legislation.

It is respectfully submitted that the Court of Appeals' decision, dated March 29, 1989, should be set aside since it misinterpreted the narrow infringement exemption of Section 271(e)(1) enacted by Congress. Senator Hatch and Representative Moorhead have an interest in having the courts properly construe federal statutes in accordance with Congressional intent set forth in the plain language and legislative history of the statute. This interest is heightened with respect to Section 271(e)(1) since both were involved actively in its passage.

Amici curiae desire to maintain the separation of powers between the judicial and legislative branches of government. The Court of Appeals' decision violates the separation of powers doctrine by taking patent rights from patent holders of inventions for medical devices, food additives, and color additives. Congress did not enact Section 271(e)(1) as the Court of Appeals has construed it.

ARGUMENT

In the view of the *amici curiae,* the Court will benefit from an understanding of the true intent of Congress as set forth in the legislative history of Section 271(e)(1). The purpose behind the enactment of Section 271(e) was to overrule the narrow aspect of the holding–denying a non-licensee use of a patented drug product, prior to the patent's expiration, for purposes related to obtaining FDA approval for a generic substitute to be sold only

after the patent expires–by the Court of Appeals for the Federal Circuit in *Roche Products Inc. v. Bolar Pharmaceutical Co.,* 733 F.2d 858 (Fed. Cir.), *cert. denied,* 469 U.S. 856 (1984). That narrow holding was seen as specifically limited to human drug testing. It is explained by the Court of Appeals itself as follows:

> The district court correctly recognized that the issue in this case is narrow: does the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable?

Roche, 733 F.2d at 861.

Congress intended to restrict the infringement exemption exclusively to this narrow holding of *Roche* limited to human drugs. Congress included the language "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs.*" 35 U.S.C. § 271(e)(1) (emphasis added).

It was never the intention of Congress to overrule *Roche* with respect to anything other than human drugs with Section 271(e)(1) as enacted in 1984. Congress' intent to limit its reversal of *Roche* to the narrow drug issue before the Court in *Roche* is expressed in the legislative history:

> In Section 202, Congress would provide that it is not an infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information *for the purpose of obtaining FDA pre-marketing approval of a drug.* The purpose of the provision is to overturn the ruling in *Roche* . . . . That case held that Bolar infringed a patent owned by Roche when, during the patent term, Bolar used the patented substance to prepare a submission to the FDA for the purpose of enabling Bolar *to market the drug* after the patent expired.

H.R. Rep. No. 857, 98th Congress, 2nd Sess., Pt.2 at 27, *reprinted in* 1984 U.S. Code and Cong. & Administrative News 2647, 2711,

fn. 18 (1984) (opinion of the Library of Congress, American Law Division) (emphasis added).

The Congressional understanding that the holding of *Roche* was specifically drug-oriented is further supported in the following legislative commentary:

> The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a *patented drug product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. Since the Committee's Subcommittee on Health and the Environment began consideration of this bill, the Court of Appeals for the Federal Circuit held that this type of experimentation is infringement.
>
> In *Roche* . . . the Court of Appeals for the Federal Circuit held that experimental use *of a drug product* prior to the expiration date of a patent claiming that drug product constitutes patent infringement, even though the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires.

Id. at 2678-2679 (emphasis added).

When Congress considered whether Section 271(e)(1) eroded these exclusive rights with respect to drug patents, it was very concerned about the potential unconstitutional "taking" that might result if the law was too broad. The Committee on the Judiciary rejected the constitutional attack chiefly because the law was limited to drug testing:

> First, the *only* activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute.

H.R. Rep. No. 857, 98th Cong., 2d Sess., pt 2, at 8, *reprinted in* 1984 U.S. Code Cong. & Admin. New 2647, 2692 (1984) (emphasis added).

In 1988, when Congress decided to add similar limited infringement exemptions for veterinary biological products, it did so by express language through an amendment to Section 271(e). *See* Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (Nov. 16, 1988).

More recently, the Honorable Senator Dennis DeConcini has introduced Senate Bill S.622 in 1989. This Bill proposes to add the term "medical device" to Section 271(e)(1), as well as to several additional portions of Section 271(e). These instances of product-specific additions are further examples that it was never Congress' intent in the 1984 Act (as amended in 1988) to include "medical devices" within the infringement exemption of Section 271(e)(1).

Respectfully submitted,

PETER BARTON HUTT
Counsel of Record
ELLEN J. FLANNERY
COVINGTON & BURLING
1201 Pennsylvania Avenue NW
P.O. Box 7566
Washington, D.C. 20044
202/662-5522

Counsel for Amici Curiae